

**BILLING CODE 6560-50-P** 

## ENVIRONMENTAL PROTECTION AGENCY

**40 CFR Part 180** 

[EPA-HQ-OPP-2019-0386; FRL-10009-14]

Fenpyroximate; Pesticide Tolerances

**AGENCY**: Environmental Protection Agency (EPA).

**ACTION**: Final rule.

**SUMMARY**: This regulation establishes and amends tolerances for residues of fenpyroximate in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES**: This regulation is effective [insert date of publication in the **Federal Register**]. Objections and requests for hearings must be received on or before [insert date 60 days after date of publication in the **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0386, is available online at <a href="http://www.regulations.gov">http://www.regulations.gov</a> or in-person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket

is (703) 305-5805.

Please note that due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <a href="https://www.epa.gov/dockets">https://www.epa.gov/dockets</a>.

**FOR FURTHER INFORMATION CONTACT**: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

### **SUPPLEMENTARY INFORMATION:**

### I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at 

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0386 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [insert date 60 days after date of publication in the **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0386, online through the Federal eRulemaking Portal at <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

Please note, that due to the public health emergency, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, and there is a temporary suspension of mail delivery to EPA (including hand deliveries). Our Docket Center staff will continue to

provide customer service via email, phone, and webform. For further information on EPA Docket Center services, docket contact information and the current status of the EPA Docket Center and Reading Room, please visit <a href="https://www.epa.gov/dockets">https://www.epa.gov/dockets</a>.

# **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of February 11, 2020 (85 FR 7708) (FRL-10005-02), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8766) by IR-4, IR-4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested to establish tolerances for residues of fenpyroximate, including its metabolites and degradates, in or on the raw agricultural commodities peanut at 0.04 parts per million (ppm); peanut, hay at 30 ppm; and tropical and subtropical, medium to large fruit, smooth, inedible peel, subgroup 24B, except banana at 0.6 ppm. Additionally, the petition requested to amend 40 CFR 180.566 by removing the established tolerances for residues of fenpyroximate in or on the raw agricultural commodities avocado at 0.15 ppm; canistel at 0.15 ppm; mango at 0.15 ppm; papaya at 0.15 ppm; sapote, black at 0.15 ppm; and star apple at 0.15 ppm. That document referenced a summary of the petition prepared by Nichino America, the registrant, which is available in the docket, http://www.regulations.gov. No comments were received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what was requested. The reason for these changes is explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe."

Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fenpyroximate including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fenpyroximate follows.

On December 5, 2019, EPA published in the **Federal Register** a final rule establishing tolerances for residues of fenpyroximate in or on multiple agricultural commodities based on the Agency's conclusion that aggregate exposure to fenpyroximate is safe for the general population, including infants and children. *See* (84 FR 66620) (FRL-10002-00). That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, cumulative risk, and the Agency's determination regarding the children's safety factor, which have not changed.

EPA's dietary exposure assessments have been updated to include the additional exposure from the new uses of fenpyroximate on peanuts, peanut hay, and the tropical and

subtropical, medium to large fruit, smooth, inedible peel subgroup 24B, except banana, including increased residues in livestock resulting from these uses. The assessment relies on tolerancelevel residues for all crops for the acute and chronic dietary assessments and assumes 100 percent crop treated (PCT) for the acute assessment and utilizes percent crop treated estimates for some commodities for the chronic assessment. EPA's aggregate exposure assessment incorporated this additional assumed dietary exposure, as well as exposure in drinking water, although this latter exposure is not impacted by the new tolerances and thus have not changed since the last assessment. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the December 5, 2019 Federal Register action as well as these new fenpyroximate tolerances can be found at http://www.regulations.gov in the document titled "Fenpyroximate: Human Health Risk Assessment for Registration Review and a Petition to Establish Tolerances for Residues in/on the Banana; Leaf Petiole Vegetable Subgroup 22B; Caneberry Subgroup 13-07A; Bushberry Subgroup 13-07B; Squash/Cucumber Subgroup 9B; and Succulent Shelled Beans; and Crop Group Conversions for Nut, Tree, Group 14-12; and Cottonseed Subgroup 20C," dated September 12, 2019 in docket ID EPA-HQ-OPP-2018-0162 and the document titled "Fenpyroximate: Human Health Risk Assessment to Support the Petition for Tolerance for Residues in/on Peanuts and Tropical and Subtropical, Medium to Large Fruit, Smooth, Inedible Peel, Subgroup 24B, Except Banana," dated March 15, 2020 in docket ID number EPA-HQ-OPP-2019-0386.

Acute dietary (food and water) risks are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): 8.6% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): 62% of the

cPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate. There are no residential uses for fenpyroximate; therefore, no short- or intermediate-term assessment was necessary. Aggregate risk is comprised solely of the dietary exposures, which are all below EPA's levels of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fenpyroximate residues.

### **IV. Other Considerations**

## A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography method with nitrogen/phosphorus detection (GC/NPD), Method S19) is available to enforce the tolerance expression. A data-gathering liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) method is also available.

The methods may be requested from: Chief, Analytical Chemistry Branch,
Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number:

(410) 305-2905; email address: residuemethods@epa.gov.

### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an

international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are no established Codex MRLs for residues of fenpyroximate in peanut or peanut hay. A Codex MRL is established for residues of fenpyroximate (parent compound only) in avocados at a lower level (0.15 ppm) than the new U.S. tolerance on the tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B, except banana, of which avocados is a part (0.6 ppm). Harmonization with the Codex MRL is not possible because the U.S. tolerance expression includes the parent compound and an additional isomer and because the U.S. use patterns require higher numerical values for the crop subgroup in order to avoid potential tolerance exceedances when label directions are followed.

## C. Revisions to Petitioned-For Tolerances

As part of the review of the petition, a revised maximum reasonable dietary burden (MRDB), including the potential contribution of peanut hay was evaluated. As indicated in EPA's regulation, 40 CFR 180.6, when finite pesticide chemical residues will be found in livestock commodities as a result of the use of a pesticide in or on animal feedstuffs, EPA will establish tolerances in livestock commodities to accommodate those residues. The additional uses of fenpyroximate on peanut (and residues on peanut, hay) result in an increase in the MRDB for beef and dairy cattle and consequently necessitate increasing tolerances for fenpyroximate residues in ruminant commodities. New tolerance levels in ruminant commodities were determined using the Langmuir model, and based on that analysis, EPA is increasing existing cattle, goat, horse, and sheep tolerances as follows: fat 0.03 ppm to 0.1 ppm, liver 0.25 ppm to

0.7 ppm, and kidney 0.25 ppm to 0.5 ppm.

## V. Conclusion

Therefore, tolerances are established for residues of fenpyroximate, including its metabolites and degradates, in or on peanut, hay at 30 ppm; peanut, at 0.04 ppm; and the tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B, except banana at 0.6 ppm.

Additionally, the following existing tolerances are increased as follows: cattle, fat from 0.03 ppm to 0.1 ppm; cattle, kidney from 0.25 ppm to 0.5 ppm; cattle, liver from 0.25 ppm to 0.7 ppm; goat, fat from 0.03 ppm to 0.1 ppm; goat, kidney from 0.25 ppm to 0.5 ppm; goat, liver from 0.25 ppm to 0.7 ppm; horse, fat from 0.03 ppm to 0.1 ppm; horse, kidney from 0.25 ppm to 0.5 ppm; horse, liver from 0.25 ppm to 0.7 ppm; sheep, fat from 0.03 ppm to 0.1 ppm; sheep, kidney from 0.25 ppm to 0.5 ppm; and sheep, liver from 0.25 ppm to 0.7 ppm.

Also, the following tolerances are removed as unnecessary due to the establishment of the above tolerances: avocado; canistel; mango; papaya; sapote, black; and star apple.

Lastly, EPA is removing, as a housekeeping measure, an expired section 18 tolerance on honey since it expired on December 31, 2013 and is no longer valid.

# **VI. Statutory and Executive Order Reviews**

This action establishes and modifies tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution,

or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as

described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

# VII. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

# **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 11, 2020.

# Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

## PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

- 2. In § 180.566:
- a. In paragraph (a)(1):
- i. Add a heading for the table.
- ii. Remove the entries for "Avocado"; "Canistel"; "Mango"; and "Papaya".
- iii. Add alphabetically the entries "Peanut" and "Peanut, hay".
- iv. Remove the entries for "Sapote, black" and "Star, apple".
- v. Add alphabetically the entry for "Tropical and subtropical, medium to large fruit, smooth, inedible peel subgroup 24B, except banana".
  - b. In paragraph (a)(2):
  - i. Add a heading for the table.
  - ii. Revise the entries for "Cattle, fat"; "Goat, fat"; "Horse, fat"; and "Sheep, fat".
  - c. In paragraph (a)(3), revise the table.
  - d. Remove and reserve paragraph (b).

The additions and revisions read as follows:

## § 180.566 Fenpyroximate; tolerances for residues.

- (a) \* \* \*
- (1) \* \* \*

Table 1 of Paragraph (a)(1)

Commodity							Parts per million			
	*	*	*	*	*	*	*			
Peanut					(	).04				
Peanut, hay					3	30				

	*	*	*	*	*	*	*		
Tropical and subtropical, medium to large fruit, smooth,									
inedible peel subgroup									
	*	*	*	*	*	*	*		

\* \* \* \* \*

(2) \* \* \*

Table 2 of Paragraph (a)(2)

	Commodity					Parts	per million	
Cattle, fat				0.1				
	*	*	*	*	*	*	*	
Goat, fat				0.1				
	*	*	*	*	*	*	*	
Horse, fat				0.1				
	*	*	*	*	*	*	*	
Sheep, fat				0.1				
	*	*	*	*	*	*	*	

(3) \* \* \*

Table 3 of Paragraph (a)(3)

Commodity	Parts per million
Cattle, kidney	0.5
Cattle, liver	0.7
Goat, kidney	0.5
Goat, liver	0.7
Horse, kidney	0.5
Horse, liver	0.7
Sheep, kidney	0.5
Sheep, liver	0.7

\* \* \* \* \*

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